UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO.

RUSSELL SURETTE,

Plaintiff,

v.

MATRIXX INITIATIVES, INC., ZICAM L.L.C.; BOTANICAL LABORATORIES, INC., AND COSTCO WHOLESALE CORPORATION,

Defendants.

COMPLAINT

Plaintiff, Russell Surette ("Surette"), for his Complaint, states as follows:

INTRODUCTION

1. This is an action to recover damages for personal injuries caused by defects in an over-the-counter cold remedy manufactured, marketed, distributed and sold as Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Gel Swabs, and Zicam Cold Remedy Gel Swabs, Kids Size ("Zicam Cold Remedy Gel") as a result of Defendants' negligence and breach of warranties. More specifically, despite the Plaintiff's use of the Zicam Cold Remedy Gel in a manner consistent with the product's labeling, marketing and instructions, the Plaintiff lost his sense of smell and has sustained a severely diminished sense of taste—irreparable impairment of two of his five senses.

PARTIES

2. Plaintiff Russell Surette resides in Middlesex County, Massachusetts.

3. Defendant Matrixx Initiatives, Inc. (hereinafter "Matrixx") is a Delaware corporation with its principal place of business in Arizona.

4. Defendant Zicam L.L.C. (hereinafter "Zicam") is an Arizona limited liability company and a wholly owned subsidiary of Matrixx with its principal place of business in Arizona.

5. Defendant Costco Wholesale Corporation (hereinafter "Costco") is a Washington corporation with its principal place of business in Washington, and it operates numerous retail stores across the country including in Massachusetts.

6. Defendant Botanical Laboratories, Inc. is a Washington corporation with its principal place of business in Washington.

7. At all times material to this Complaint, each of the Defendants transacted, solicited or otherwise conducted business in Massachusetts.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 in that complete diversity of citizenship exits between the Plaintiff and the Defendants and Surette's claims are for substantially in excess of $75,000.

9. This Court has personal jurisdiction over the Defendants pursuant to the Massachusetts Long Arm Statute, Mass. Gen. Laws c. 223A § 3(a), (c) or (d).

10. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(a)(2) or (3).

FACTS COMMON TO ALL COUNTS

11. At all times material to this Complaint, Defendants Matrixx and Zicam developed, manufactured and marketed over-the-counter pharmaceuticals, including Zicam Cold Remedy Gel.

12. Upon information and belief, at all times material to this Complaint, Botanical Laboratories, Inc. manufactured and packaged Zicam Cold Remedy Gel for sale and distribution by Defendants Matrixx and Zicam.

13. At all times material to this Complaint, Defendant Costco marketed, distributed and sold Zicam Cold Remedy Gel throughout the United States and specifically in Massachusetts.

14. At all times material to this Complaint, each of the Defendants knew or reasonably should have known that Zicam Cold Remedy Gel would be distributed throughout the United States and specifically in Massachusetts.

15. At all times material to this Complaint, the Defendants knew or should have known that their acts would have consequences throughout the United States and specifically in Massachusetts.

16. Zicam Cold Remedy Gel is packaged in a variety of forms, including a nasal pump with nasal gel and a swab with nasal gel, which are developed, manufactured, marketed, distributed and sold by the Defendants.

17. The nasal pump and swab formats used in Zicam Cold Remedy Gel were intended to deliver and apply the nasal gel within the nose of the user.

18. Zicam Cold Remedy Gel contains divalent ionized zinc in the form of zinc gluconate, which is listed as the product's active ingredient under the name "Zincum Gluconium 2x."

19. Zinc gluconate contains a divalent zinc ion.

20. Zinc gluconate is a chemical compound characterized as a "zinc salt."

21. When used as directed, the nasal pump and swab formats deliver the Zicam Cold Remedy Gel to the nasal membranes of the user.

22. Zicam Cold Remedy Gel labels tell the user that it will reduce duration and severity of the common cold and such symptoms as sore throat, stuffy nose, sneezing, coughing and congestion.

23. Zicam Cold Remedy Gel is marketed as a homeopathic remedy and is not a "drug" as defined in §321 of the Federal Food, Drug and Cosmetic Act, Chapter 675, 52 Stat. 1040, 21 U.S.C. §321.

24. Zicam Cold Remedy Gel is not and has not been approved by the United States Food and Drug Administration (the "FDA") for safety or efficacy.

25. Zicam Cold Remedy Gel's labeling has never been approved by the FDA.

26. On or about September 11, 2008, Surette purchased a Zicam Cold Remedy Gel two pack in the nasal pump format from a Costco store located in Everett, Massachusetts and owned and operated by Costco Wholesale Corporation.

27. In or about April 2009, Surette used the Zicam Cold Remedy Gel as directed on the packaging.

28. Upon using Zicam Cold Remedy Gel Surette felt an immediate burning sensation in his nose, and by the next morning Surette realized he no longer had a sense of smell.

29. Also, Surette's sense of taste was severely diminished as a result of his use of Zicam Cold Remedy Gel.

30. On or about June 16, 2009, the FDA issued a warning to consumers to stop using, and to discard, Zicam Cold Remedy Gel because these products can cause the loss of sense of smell, a condition called anosmia.

31. On or about June 16, 2009, the FDA issued a Warning Letter to Defendant Matrixx stating in pertinent part: that the FDA was unaware of any data establishing that the Zicam Cold Remedy Gel intranasal products are generally recognized as safe and effective for the intended users identified in the labeling; that to the contrary, there is evidence that these products pose a serious safety risk to consumers; that the FDA had received more than 130 reports of anosmia and some reports from individuals of a loss of the sense of taste associated with these products; that published scientific literature exists stating that various salts of zinc can damage olfactory function in animals and humans; that the FDA became aware that Matrixx had received more than 800 reports relating to the loss of sense of smell associated with Zicam Cold Remedy Gel intranasal products, and that Zicam Cold Remedy Gel intranasal products do not bear adequate warnings regarding the risk of anosmia associated with the products. A true copy of the FDA Letter of June 16, 2009 is attached hereto as Exhibit "A."

32. On or about June 17, 2009, Defendant Matrixx suspended all shipments of Zicam Cold Remedy Gel throughout the United States.

33. On or about June 18, 2009, the then acting president of Matrixx, William Hemelt, admitted that Matrixx failed to notify the FDA of the 800 consumer complaints about Zicam Cold Remedy Gel.

34. Surette's loss of his sense of smell and his diminished sense of taste continue through the date of this Complaint.

35. Surette's loss of his senses of smell and taste continues, despite the care of his primary care physician and an ear, nose and throat specialist.

36. Testing done on Surette has eliminated other possible causes of anosmia than his use of Zicam Cold Remedy Gel.

37. With the loss of his sense of smell and diminished sense of taste, Surette has suffered and continues to suffer, among other things, impairment of his enjoyment and experience of life including diminished pleasure eating and drinking, engaging in recreational outdoor activities and associations of memory with smells he can no longer sense.

38. Surette also has an increased risk of harm to himself compared to persons with an intact sense of smell because, for example, he is unable to detect the smell of gas, gasoline, smoke or fire.

39. Surette's loss of his sense of smell and his diminished sense of taste are more likely than not permanent.

40. Surette did not misuse Zicam Cold Remedy Gel or alter the product or its packaging in any way and used the product in a reasonably foreseeable manner.

41. Surette was unaware that Zicam Cold Remedy Gel created an unreasonable risk of personal injury.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

42. Surette brings this action as a class action pursuant to Federal Rules of Civil Procedure Rule 23 and Massachusetts General Laws, Chapter 93A, section 9(2) and all similar such consumer protections laws in other states on behalf of a Class consisting of all those who

purchased or used Zicam Cold Remedy Gel containing zinc salts and used the same in a manner consistent with the product's labeling, marketing and instructions from June 30, 2006 to the present, and who suffered a diminishment or loss of the sense of smell or diminishment of the sense of taste or who suffered economic harm as a result of such purchases.

43. The members of the Class are so numerous that joinder of all members is impracticable. As of June 2009 there were reports now known to the FDA of more than 800 persons who suffered anosmia as a result of the use of Zicam Cold Remedy Gel. While the exact number of Class members is unknown to the Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least 1,000 members in the proposed class. The number of members is likely to greatly exceed 1,000 as Matrixx has reported in its public disclosures that the sales of this product accounted for forty percent (40%) of its net sales in fiscal year 2009 which totaled $32,543,000.00 through September 30, 2009. With a retail price under $10 per unit, these sales figures indicate the magnitude of the amount of product in the stream of commerce.

44. Surette's claims are typical of the claims of the members of the Class who are similarly affected by the Defendants' wrongful conduct complained of in this Complaint herewith.

45. Surette will fairly and adequately represent and protect the interests of the members of the Class and has retained counsel competent and experienced in class actions and product liability litigation.

46. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. The common questions in this action include:

a) whether Zicam Cold Remedy Gel is defective or unsafe;

b) whether Defendants concealed material information about the safety of or defects in Zicam Cold Remedy Gel;

c) whether Defendants intentionally, recklessly or negligently misrepresented the safety of Zicam Cold Remedy Gel;

d) whether Defendants were negligent in the design of Zicam Cold Remedy Gel;

e) whether the Defendants failed to adequately warn consumers of the defects and unsafe condition of Zicam Cold Remedy Gel;

f) whether Defendants breached the express and implied warranties of merchantability and fitness for a particular purpose as to Zicam Cold Remedy Gel;

g) whether Surette and Class members were injured as a result of Defendants' conduct and the extent and measure of such injury, and

h) whether Defendants' conduct, as alleged, constituted unfair or deceptive acts or practices in violation of M.G.L. c. 93A, §2 and the regulations promulgated thereunder or similar statutes and regulations in other states.

47. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy as joinder of all members is impracticable and the members' claims can best be managed as a class action.

Count One
(Breach of the Warranties)

48. Surette incorporates herein paragraphs 1 through 48 of this Complaint.

49. Defendants expressly and impliedly warranted and represented that Zicam Cold Remedy Gel was of merchantable quality and fit for the particular purposes of a safe and effective remedy to reduce the severity and duration of the common cold.

50. Defendants expressly and impliedly warranted to Surette that Zicam Cold Remedy Gel was safe and effective when used as directed.

51. Defendants' breached these warranties in that Zicam Cold Remedy Gel was not of merchantable quality and was not fit for the particular purposes but instead was defective and unsafe.

52. Defendants' breach of warranties directly and proximately caused Surette's harm including but not limited to anosmia, a diminished sense of taste, pain and suffering, impairment of his enjoyment of life, and economic damage.

53. Surette brings this claim on behalf of himself and the Class members, and his claim is representative of theirs.

54. Class members have suffered injury and damage similar to Surette.

Count Two
(Negligence)

55. Surette incorporates herein paragraphs 1 through 54 of this Complaint.

56. Defendants owed a duty to Surette not to place products in the stream of commerce and marketplace that would result in harm to consumers like Surette and to adequately warn him of the dangers and harmful effects of Zicam Cold Remedy Gel.

57. Defendants owed a duty to Surette to use due care in the design and testing of Zicam Cold Remedy Gel.

58. Defendants breached their duties to Surette by their acts or omissions that include, but are not limited to:

a. Upon information and belief, failing to ensure that the ingredients in Zicam Cold Remedy Gel were safe;

b. Upon information and belief, failing to ensure that the delivery system distributed and sold as the means to apply Zicam Cold Remedy Gel was safe;

c. Upon information and belief, failing to conduct proper testing of Zicam Cold Remedy Gel;

d. Failing to warn consumers adequately that Zicam Cold Remedy Gel was dangerous and presented a risk of a loss of smell or loss of taste;

e. Upon information and belief, failing to pay attention to, disclose and report, adequately investigate and account for or remedy consumer complaints that Zicam Cold Remedy Gel caused them anosmia;

f. Promoting and selling Zicam Cold Remedy Gel as safe and effective when they knew or should have known that Zicam Cold Remedy Gel was dangerous;

g. Selling Zicam Cold Remedy Gel to be used intranasally and instructing users to apply it intranasally;

h. Failing to design the product in accordance with prevailing industry standards in a manner that would have eliminated unreasonable risk of injury to foreseeable users.

i. Failing to manufacture the product in a manner that would have eliminated unreasonable risk of injury to foreseeable uers.

59. As a direct and proximate result of the Defendants' negligence, Surette suffered and continues to suffer harm including, but not limited to anosmia, a diminished sense of taste, pain and suffering and impairment of his enjoyment of life.

60. Surette brings this claim on behalf of himself and the Class members, and his claim is representative of theirs.

61. Class members have suffered injury and damage similar to Surette.

Count Three
(Misrepresentation)

62. Surette incorporates herein paragraphs 1 through 61 of this Complaint.

63. Defendants intentionally, recklessly or negligently misrepresented the safety of Zicam Cold Remedy Gel.

64. Upon information and belief, Defendants misrepresented or concealed such material adverse information that they had a duty to disclose to Surette, the FDA, and the general public.

65. Defendants made these misrepresentations and omissions about the safety of Zicam Cold Remedy Gel in its packaging, labeling, marketing and advertising.

66. These misrepresentations and omissions were material.

67. Defendants knew or should have known, or were negligent in not knowing, of the falsity of these representations and the necessity of disclosing the omitted material information about the lack of safety of Zicam Cold Remedy Gel.

68. Defendants knew or should have foreseen that Surette would rely on such misrepresentations and omissions.

69. Surette reasonably relied to his detriment on Defendants' false representations and omissions.

70. As a result of his reasonable reliance on Defendants' false representations and omissions, Surette suffered and continues to suffer harm including, but not limited to anosmia, a diminished sense of taste, pain and suffering, impairment of his enjoyment of life, and economic damage.

71. Surette brings this claim on behalf of himself and the Class members, and his claim is representative of theirs.

72. Class members have suffered injury and damage similar to Surette.

Count Four
(M.G.L. c. 93A - Consumer Protection Act and Similar Consumer Protection Laws in Other States)

73. Surette incorporates herein paragraphs 1 through 72 of this Complaint.

74. By reason of the Defendants' conduct as set forth above in this Complaint, the Defendants engaged in unfair or deceptive acts or practices within the meaning of M.G.L. c. 93A and other similar consumer protection laws of other states, undertaken in the course of trade or commerce.

75. As to Surette, the aforementioned conduct of the Defendants occurred substantially and primarily within the Commonwealth of Massachusetts.

76. Surette and the Class members fulfilled the notice requirements of M.G.L. c. 93A and other similar consumer protection laws of other states by sending the demand letter by certified and regular mail to the Defendants, true copies of which are attached hereto as Exhibits "B" and "C." The demand letters were sent no less than 30 days prior to the commencement of this action.

77. Defendants have failed to tender a reasonable offer of settlement to Surette and the Class members before the expiration of the thirty days after service and at any time prior to the commencement of this action.

78. As a direct result of Defendants' unfair or deceptive acts or practices, Surette was injured and suffered actual damages, including, but not limited to anosmia, a diminished sense of taste, pain and suffering, impairment of his enjoyment of life, and economic harm in the amount of the purchase price of the product.

79. The unfair or deceptive acts or practices of defendants as alleged herein were willful or knowing violations of M.G.L. c. 93A, §2, within the meaning of M.G.L. c. 93A, §9(3).

80. Surette brings this claim on behalf of himself and the Class members, and his claim is representative of theirs.

81. Class members have suffered injury and damage similar to Surette.

DEMAND FOR A JURY TRIAL

Plaintiff hereby demands a jury trial as to all claims so triable.

PRAYERS FOR RELIEF

WHEREFORE, Russell Surette, on behalf of himself and all other Class members, respectfully requests as follows:

a. Determination that this action is a proper class action and certification of the Class under Rule 23 of the Federal Rules of Civil Procedure or Massachusetts General Laws chapter 93A, section 9(2) or applicable and comparable laws of other states in the United States;

b. Judgment in favor of Russell Surette and the other Class members on each count of this Complaint;

c. Award of compensatory and other damages in favor of Russell Surette and the other Class members against each Defendant for injuries sustained as a result of Defendants' wrongdoing;

d. Award of economic damages to Russell Surette and other Class members in the amount of the total purchase price paid for the Zicam Cold Remedy Gel;

e. Award of interest thereon from date of injury through date of judgment;

f. Award of attorneys' fees and multiple damages under M.G.L. c. 93A or comparable and applicable laws of other states to Surette and Class members;

g. Award of reasonable costs and expenses incurred in this action incurred by Russell Surette and the other members of the Class, and

h. Grant of such other and further legal and equitable relief as the Court deems just and proper to Russell Surette and the other Class members.

Respectfully submitted,
RUSSELL SURETTE
By his attorneys,

/s/ Dennis J. Kelly
Dennis J. Kelly, BBO #266340
dkelly@burnslev.com
Lawrence P. Murray, BBO #561835
lmurray@burnslev.com
BURNS & LEVINSON LLP
125 Summer Street
Boston, MA 02110-1624
Phone - (617) 345-3000
Fax - (617) 345-3299

Dated: June 30, 2010

Exhibit A

Inspections, Compliance, Enforcement, and Criminal Investigations

Matrixx Initiatives, Inc. AKA Zicam LLC 6/16/09

Department of Health and Human Services

Public Health Service
Food and Drug Administration

WARNING LETTER

June 16, 2009

VIA FAX & FEDEX

RETURN RECEIPT REQUESTED

William J. Hemelt, Acting President, CFO and COO
Matrixx Initiatives, Inc
8515 East Anderson Drive
Scottsdale, AZ 85255

Dear Mr. Hemelt:

This letter concerns your firm's marketing of the products Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Gel Swabs, and Zicam Cold Remedy Swabs, Kids Size.

FDA has concluded that these products may pose a serious risk to consumers who use them. Specifically, FDA has received more than 130 reports of anosmia, (loss of sense of smell, which in some cases can be long-lasting or permanent), associated with use of these products.

To protect consumers, and in light of the violations described below, we ask that within fifteen working days of receipt of this letter, you notify this office in writing of the specific steps that you have taken to correct the violations.

These products are available without a prescription, and they contain zinc gluconate (identified as zincum gluconicum on their labels) as their active ingredient. All are administered by direct application to the nasal cavity and, as described in the labeling, are intended for use in "adults and children 3 years of age and older (with adult supervision)." These products are referred to hereafter as the "Zicam Cold Remedy intranasal products."

According to the labeling accompanying the Zicam Cold Remedy intranasal products, each of these products "reduces" the "duration of the common cold" and the "severity of cold symptoms," including specifically "sore throat • stuffy nose •sneezing • coughing • congestion." These claims make these products drugs, as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body of man or other animals.

We are not aware of any data establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the uses identified in their labeling.[1] On the contrary, as described below, there is evidence that these products pose a serious safety risk to consumers. Because they are not generally recognized as safe and effective for their labeled uses, these products are new drugs, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p).

Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. There are no approved new drug applications (NDAs) on file with FDA for any of the Zicam Cold Remedy intranasal products; you market them without FDA approval.

We recognize that the labeling for Zicam Cold Remedy intranasal products identifies them as homeopathic drug products with an active ingredient measured in homeopathic strength—Zincum Gluconicum 2X. Nothing in the Act or the regulations issued under it exempts homeopathic drugs from the new drug approval requirements. We acknowledge that many homeopathic drug products are manufactured and distributed without FDA approval under enforcement policies set out in the FDA's Compliance Policy Guide entitled, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)" (the CPG). The enforcement discretion set forth in the CPG is not unlimited, however. The CPG states that it "delineates those conditions under which homeopathic drugs may *ordinarily* be marketed in the U.S." (emphasis added) The qualifying word "ordinarily" indicates that the CPG specifically contemplates that there may be circumstances where a product that otherwise may meet the conditions set forth in the CPG may nevertheless be subject to enforcement action.

A significant and growing body of evidence substantiates that the Zicam Cold Remedy intranasal products may pose a serious risk to consumers who use them. Specifically, FDA has received more than 130 reports of anosmia (loss of sense of smell, which in some cases can be long-lasting or permanent),associated with use of these products; some individuals also report loss of sense of taste.[2] By comparison, FDA has received few reports of anosmia associated with other widely-used intranasal products for treatment of the common cold that are marketed subject to approved NDAs or according to an OTC drug monograph. Further, there is evidence in the published scientific literature that various salts of zinc can damage olfactory function in animals and humans.

A homeopathic drug product marketed without an approved NDA is not subject to the enforcement discretion set forth in the CPG when there is evidence of a safety risk associated with the product, as is the case for the Zicam Cold Remedy intranasal products. Under these

circumstances, the Agency enforces the Act's new drug approval requirement, a provision that is essential to protect the public health by holding firms responsible for demonstrating, based on adequate and well-controlled clinical investigations, that a product is safe and effective for each of its intended uses before marketing it. Therefore, an approved NDA is required for the Zicam Cold Remedy intranasal products, regardless of their homeopathic status. Your introduction of the Zicam Cold Remedy intranasal products into interstate commerce, without an approved application, violates sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a).

Additionally, Zicam Cold Remedy intranasal products are misbranded under section 502(f)(2) of the Act, 21 U.S.C. § 352(f)(2), because their labeling does not bear adequate warnings regarding the risk of anosmia associated with the product. In light of this failure to bear adequate warnings, these products are also misbranded under section 502(a) of the Act, 21 U.S.C. § 352(a), taking into account the considerations set forth in section 201(n) of the Act, 21 U.S.C. § 321(n).

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations. A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/cder/regulatory/applications/default.htm[1]. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, Maryland 20857.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the corrections. Furthermore, please advise this office what actions you will take to address product that you have already distributed.

In addition to the reports FDA has received directly from consumers, the agency is aware that Matrixx appears to have more than 800 reports related to loss of sense of smell associatedwith Zicam Cold Remedy intranasal products. Please contact Elisabeth Walther at the contact information below to arrange submission of all reports you have related to loss of sense of smell associated with Zicam Cold Remedy intranasal products. Please indicate which of these reports have been previously submitted to FDA.

Additionally, if another firm or firms manufacture the products identified above, your reply should include the name and address of all such firms. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Address your reply to the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, **Attention: Elisabeth Walther, Pharmacist**.

Sincerely,

Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

[1] Under the Agency's OTC drug review, FDA has adopted a final monograph that establishes conditions under which OTC cold, cough, allergy, bronchodilator, and anti-asthmatic drug products, in forms suitable for oral, inhalant, or topical administration, are generally recognized as safe and effective. 21 CFR Part 341 (the OTC Cold Cough monograph). This final monograph covers products intended to treat the same conditions for which Zicam is labeled (i.e., treatment of the common cold and cold symptoms). Although homeopathic drugs are excluded from the OTC drug review (37 F.R. 9464, 9466 (May 11, 1972)), we note that the OTC Cold Cough monograph does not include any products in any dosage form containing zinc or any salt of zinc as their active ingredient.

[2] We note that loss of sense of smell can have serious consequences. For example, patients with anosmia may not be able to detect the smell of a gas leak, smoke, or spoiled food. Loss of sense of taste can have a major impact on an individual's quality of life.

Links on this page:

1. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm

Exhibit B

BURNS & LEVINSON LLP

125 SUMMER STREET BOSTON, MA 02110
T 617.345.3000 F 617.345.3299
BURNSLEV.COM

March 19, 2010

VIA REGULAR MAIL and
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William J. Hemelt,
Acting President, CFO, CEO
Matrixx Initiatives, Inc.
8515 E. Anderson Drive
Scottsdale, AZ 85255

James D. Sinegal,
President
Costco Wholesale Corporation
999 Lake Drive
Issaquah, WA 98027

Zicam, L.L.C.
William J. Hemelt,
Manager
4742 N. 24th St., Suite 455
Phoenix, AZ 85016-4856

Botanical Laboratories, Inc.
Jim Thornton,
President
1441 W. Smith Road
Ferndale, WA 98248-8933

Re: DEMAND FOR RELIEF UNDER M.G.L.A. c. 93A

Dear Sir/Madam:

We represent Russell Surette, individually and as a representative of the class of all persons similarly situated, as defined below. This letter is a written demand for relief pursuant to Massachusetts General Laws, Chapter 93A, §9(2) and (3) ("Massachusetts Consumer Protection Statute") as well as pursuant to all similar state consumer protection statutes, nationwide, requiring such a demand.

CLAIMANT AND THE CLASS

Russell Surette ("Claimant"), a Massachusetts resident, makes this demand for relief for himself and on behalf of a class comprised of Massachusetts residents and residents of other states who purchased and used Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Gel Swabs and Zicam Cold Remedy Gel Swabs, Kids Size (hereinafter collectively "Zicam Cold Remedy Gel") and suffered a diminishment (hyposmia) or loss of the sense of smell (anosmia) in Massachusetts, as a result of Respondents [your] violation of the Consumer Protection Statute, and on behalf of all similarly situated persons who purchased and used Zicam Cold Remedy Gel and suffered similar injury in any other state (the "Class"), during the period from April 20, 2006 through the present (the "Class Period").

anosmia were made to mislead the Claimant and the Class members to purchase and use Zicam Cold Remedy Gel.

Further evidence supporting the claims of Claimant and the Class consists of an FDA Warning Letter sent to Respondent Matrixx on or about June 16, 2009 (the "Warning Letter"). The Warning Letter to Respondent Matrixx stated in pertinent part: that the FDA was unaware of any data establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the intended users identified in the labeling; that to the contrary there is evidence that these products pose a serious safety risk to consumers; that the FDA had received more than 130 reports of anosmia, and some reports from individuals of a loss of the sense of taste associated with these products; that published scientific literature exists stating that various salts of zinc can damage olfactory function in animals and humans; that the FDA became aware that Matrixx appeared to have more than 800 reports related to the loss of sense of smell associated with use of Zicam Cold Remedy intranasal products, and that Zicam Cold remedy intranasal products did not bear adequate warnings regarding the risk of anosmia associated with the products.

Respondents expressly warranted to Claimant and the Class members that Zicam Cold Remedy Gel was safe and effective when used as directed. In addition, Respondents impliedly warranted that the products were of merchantable quality and fit for their intended purpose, to wit, as a safe and effective remedy for the common cold. Respondents breached these warranties in that Zicam Cold Remedy Gel was defective, unsafe, and unreasonably dangerous and was not of merchantable quality nor fit for the intended purpose.

During the Class Period, Claimant purchased a Zicam Cold Remedy Gel two pack from a Costco store located in Massachusetts which is owned and operated by Costco Wholesale Corporation. Claimant used the Zicam Cold Remedy Gel as directed on the packaging during the Class period. After using Zicam Cold Remedy Gel, Claimant felt an immediate burning sensation in his nose. Although the pain persisted, it being the end of the day, the Claimant went to bed. That next morning, Claimant realized he had no sense of smell. Claimant's loss of his sense of smell has continued to the date of this letter. Furthermore, Claimant's sense of taste had been severely diminished which loss has also continued through the date of this letter. The Class members have suffered injury similar to the Claimant's after purchasing and using Zicam Cold Remedy Gel, as directed, during the Class Period as a result of the Respondents' use or employment of the unfair or deceptive acts or practices described above.

Respondents' conduct, as described in this letter was a willful or knowing violation of Massachusetts General Laws, Chapter 93A, §9(3), and such similar consumer protection laws in other states, entitling the Claimant and Class members to recover up to three but not less than two times his or her actual damages in addition to attorneys' fees and costs.

Claimant purchased and used Zicam Cold Remedy Nasal Gel during the Class Period, as did members of the Class. The size of the Class is reasonably believed to be at least in the thousands.

FACTUAL BASIS FOR THE CLAIMS

During the Class Period, Matrixx Initiatives, Inc. ("Matrixx"), Costco Wholesale Corporation ("Costco"), Zicam L.L.C., and Botanical Laboratories, Inc.("Botanical") (hereinafter collectively the "Respondents") engaged in unfair or deceptive acts or practices including, but not limited to, the following:

Matrixx and Zicam L.L.C. developed, manufactured and marketed over-the-counter pharmaceuticals, including Zicam Cold Remedy Gel. Botanical manufactured and packaged Zicam Cold Remedy Gel for sale and distribution by Matrixx and Zicam. Costco marketed, distributed and sold Zicam Cold Remedy Gel. The Respondents were aware and specifically intended that Zicam Cold Remedy Gel would be marketed, distributed, and sold, and purchased by consumers, throughout the United States and specifically in Massachusetts.

Respondents Matrixx, Zicam L.L.C. and Costco sold Zicam Cold Remedy Gel to consumers in Massachusetts and throughout the United States by means of false and misleading statements, labeling, advertising, marketing and promotion. The Respondents represented and warranted that Zicam Cold Remedy Gel was safe and effective as a cold remedy and omitted material facts including the risk of hyposmia and anosmia to consumers from the use of the products. These representations and warranties were false and deceptive and were intended to and did mislead consumers into believing that Zicam Cold Remedy Gel is safe and effective for use as a remedy for the common cold. Furthermore, the Respondents failed to warn consumers adequately regarding the risk of hyposmia and anosmia resulting from use of the products.

Contrary to the Respondents representations and warranties by the, Zicam Cold Remedy Gel is proven neither safe nor effective as a remedy for the common cold and is unreasonably dangerous in that the use of the product can lead to hyposmia and anosmia. Respondents Matrixx, Zicam L.L.C. and Botanical knew or should have known that Zicam Cold Remedy Gel was defective and that there was a substantial likelihood that the defect would lead to hyposmia or anosmia in consumers who used the products. Respondents Matrixx, Zicam L.L.C. and Botanical concealed the danger of hyposmia and anosmia by, among other things, withholding information about claims of anosmia made by users of Zicam Cold Remedy Gel and by reporting that the products had been fully and properly tested when they had not. As of July 2009, Respondent Matrixx had received more than 800 reports from consumers experiencing a loss of sense of smell associated with the use of Zicam Cold Remedy Gel. Yet these reports were not disclosed by Matrixx to consumers or the Food and Drug Administration ("FDA") prior to July of 2009. These concealments and omissions of facts about the defective nature of Zicam Cold Remedy Gel, the lack of safety and efficacy of the products and the risk of hyposmia and

INJURIES SUFFERED

Claimant's and the Class members' similar injuries were caused by the Respondents' use or employment of unfair or deceptive trade acts or practices, as described above. Claimant and the other Class members have incurred actual damages as a result of their purchase and use of Zicam Cold Remedy Gel during the Class period. These damages include, but are not limited to: permanent anosmia or hyposmia; diminishment or loss of the sense of taste; mental and emotional distress; pain and suffering; loss of enjoyment of everyday activities and severely diminished quality of life, and increased risk of harm to himself and others as compared to people with an intact sense of smell.

DEMAND FOR RELIEF

The conduct set forth above demonstrably constitutes acts or practices declared to be unfair or deceptive under Massachusetts General Laws, Chapter 93A and the regulations promulgated thereunder by the Attorney General and under consumer protection statutes in other states. Under the Massachusetts Attorney General's regulations, "claims relating to the ...safety...or the utility..." of the product are material. 940 C.M.R. §3.05(1). Furthermore, 940 C.M.R. 3.08(2) provides as follows:

> 2) Warranties. It shall be an unfair and deceptive act or practice to fail to perform or fulfill any promises or obligations arising under a warranty. The utilization of a deceptive warranty is unlawful.

A breach of an express or implied warranty constitutes a violation of M.G.L. 93A. *Maillet v. ATF-Davidson Co.*, 407 Mass. 185, 193 (1990); *Glyptal Inc. v. Engelhard Corp.*, 801 F. Supp. 887, 899 (D. Mass. 1992)("Breaches of express and implied warranties constitute a virtual per se violation of [G.L. c. 93A, §2].")

Therefore, on the basis of the facts set forth herein, the Claimant, for himself and on behalf of the Class members demands that Respondents:

1. Compensate Claimant and the Class members for the actual damages incurred by them; and

2. Reimburse Claimant and Class members for their reasonable attorneys' fees and expenses incurred in bringing this claim.

Please be advised the Respondents have thirty (30) days under the Massachusetts Consumer Protection Statute in which to tender a reasonable offer of settlement. If Respondents

refuse in bad faith to grant relief upon this demand within the applicable period and with knowledge or reason to know that their acts or practices violated the Consumer Protection Statute or consumer protection laws of other states, the Claimant and the Class are entitled to up to three but not less than two times their actual damages. Should Respondents fail to grant such timely relief, the Claimant, on behalf of himself and the Class members, will institute a claim seeking treble damages, interest, attorneys' fees and costs.

Please send your response to the undersigned.

Sincerely yours,

Dennis J. Kelly

cc: Russell Surette, Client
Lawrence P. Murray, Esquire

Exhibit C

BURNS & LEVINSON LLP

125 SUMMER STREET BOSTON, MA 02110
T 617.345.3000 F 617.345.3299
BURNSLEV.COM

March 30, 2010

VIA REGULAR MAIL and
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Zicam, L.L.C.
William J. Hemelt,
Manager
2375 E. Camelback Rd Ste 500
Phoenix, AZ 85016-4856

Re: DEMAND FOR RELIEF UNDER M.G.L.A. c. 93A

Dear Mr. Hemelt:

We represent Russell Surette, individually and as a representative of the class of all persons similarly situated, as defined below. This letter is a written demand for relief pursuant to Massachusetts General Laws, Chapter 93A, §9(2) and (3) ("Massachusetts Consumer Protection Statute") as well as pursuant to all similar state consumer protection statutes, nationwide, requiring such a demand.

CLAIMANT AND THE CLASS

Russell Surette ("Claimant"), a Massachusetts resident, makes this demand for relief for himself and on behalf of a class comprised of Massachusetts residents and residents of other states who purchased and used Zicam Cold Remedy Nasal Gel, Zicam Cold Remedy Gel Swabs and Zicam Cold Remedy Gel Swabs, Kids Size (hereinafter collectively "Zicam Cold Remedy Gel") and suffered a diminishment (hyposmia) or loss of the sense of smell (anosmia) in Massachusetts, as a result of Respondents [your] violation of the Consumer Protection Statute, and on behalf of all similarly situated persons who purchased and used Zicam Cold Remedy Gel and suffered similar injury in any other state (the "Class"), during the period from April 20, 2006 through the present (the "Class Period").

Claimant purchased and used Zicam Cold Remedy Nasal Gel during the Class Period, as did members of the Class. The size of the Class is reasonably believed to be at least in the thousands.

FACTUAL BASIS FOR THE CLAIMS

During the Class Period, Matrixx Initiatives, Inc. ("Matrixx"), Costco Wholesale Corporation ("Costco"), Zicam L.L.C., and Botanical Laboratories, Inc.("Botanical") (hereinafter collectively the "Respondents") engaged in unfair or deceptive acts or practices including, but not limited to, the following:

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Respondents Matrixx, Zicam L.L.C. and Costco sold Zicam Cold Remedy Gel to consumers in Massachusetts and throughout the United States by means of false and misleading statements, labeling, advertising, marketing and promotion. The Respondents represented and warranted that Zicam Cold Remedy Gel was safe and effective as a cold remedy and omitted material facts including the risk of hyposmia and anosmia to consumers from the use of the products. These representations and warranties were false and deceptive and were intended to and did mislead consumers into believing that Zicam Cold Remedy Gel is safe and effective for use as a remedy for the common cold. Furthermore, the Respondents failed to warn consumers adequately regarding the risk of hyposmia and anosmia resulting from use of the products.

Contrary to the Respondents representations and warranties by the, Zicam Cold Remedy Gel is proven neither safe nor effective as a remedy for the common cold and is unreasonably dangerous in that the use of the product can lead to hyposmia and anosmia. Respondents Matrixx, Zicam L.L.C. and Botanical knew or should have known that Zicam Cold Remedy Gel was defective and that there was a substantial likelihood that the defect would lead to hyposmia or anosmia in consumers who used the products. Respondents Matrixx, Zicam L.L.C. and Botanical concealed the danger of hyposmia and anosmia by, among other things, withholding information about claims of anosmia made by users of Zicam Cold Remedy Gel and by reporting that the products had been fully and properly tested when they had not. As of July 2009, Respondent Matrixx had received more than 800 reports from consumers experiencing a loss of sense of smell associated with the use of Zicam Cold Remedy Gel. Yet these reports were not disclosed by Matrixx to consumers or the Food and Drug Administration ("FDA") prior to July of 2009. These concealments and omissions of facts about the defective nature of Zicam Cold Remedy Gel, the lack of safety and efficacy of the products and the risk of hyposmia and anosmia were made to mislead the Claimant and the Class members to purchase and use Zicam Cold Remedy Gel.

Further evidence supporting the claims of Claimant and the Class consists of an FDA Warning Letter sent to Respondent Matrixx on or about June 16, 2009 (the "Warning Letter"). The Warning Letter to Respondent Matrixx stated in pertinent part: that the FDA was unaware of any data establishing that the Zicam Cold Remedy intranasal products are generally recognized as safe and effective for the intended users identified in the labeling; that to the contrary there is evidence that these products pose a serious safety risk to consumers; that the FDA had received more than 130 reports of anosmia, and some reports from individuals of a loss of the sense of taste associated with these products; that published scientific literature exists stating that various salts of zinc can damage olfactory function in animals and humans; that the FDA became aware that Matrixx appeared to have more than 800 reports related to the loss of sense of smell associated with use of Zicam Cold Remedy intranasal products, and that Zicam Cold remedy intranasal products did not bear adequate warnings regarding the risk of anosmia associated with the products.

Respondents expressly warranted to Claimant and the Class members that Zicam Cold Remedy Gel was safe and effective when used as directed. In addition, Respondents impliedly warranted that the products were of merchantable quality and fit for their intended purpose, to wit, as a safe and effective remedy for the common cold. Respondents breached these warranties in that Zicam Cold Remedy Gel was defective, unsafe, and unreasonably dangerous and was not of merchantable quality nor fit for the intended purpose.

During the Class Period, Claimant purchased a Zicam Cold Remedy Gel two pack from a Costco store located in Massachusetts which is owned and operated by Costco Wholesale Corporation. Claimant used the Zicam Cold Remedy Gel as directed on the packaging during the Class period. After using Zicam Cold Remedy Gel, Claimant felt an immediate burning sensation in his nose. Although the pain persisted, it being the end of the day, the Claimant went to bed. That next morning, Claimant realized he had no sense of smell. Claimant's loss of his sense of smell has continued to the date of this letter. Furthermore, Claimant's sense of taste had been severely diminished which loss has also continued through the date of this letter. The Class members have suffered injury similar to the Claimant's after purchasing and using Zicam Cold Remedy Gel, as directed, during the Class Period as a result of the Respondents' use or employment of the unfair or deceptive acts or practices described above.

Respondents' conduct, as described in this letter was a willful or knowing violation of Massachusetts General Laws, Chapter 93A, §9(3), and such similar consumer protection laws in other states, entitling the Claimant and Class members to recover up to three but not less than two times his or her actual damages in addition to attorneys' fees and costs.

INJURIES SUFFERED

Claimant's and the Class members' similar injuries were caused by the Respondents' use or employment of unfair or deceptive trade acts or practices, as described above. Claimant and the other Class members have incurred actual damages as a result of their purchase and use of Zicam Cold Remedy Gel during the Class period. These damages include, but are not limited to: permanent anosmia or hyposmia; diminishment or loss of the sense of taste; mental and emotional distress; pain and suffering; loss of enjoyment of everyday activities and severely diminished quality of life, and increased risk of harm to himself and others as compared to people with an intact sense of smell.

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2. Reimburse Claimant and Class members for their reasonable attorneys' fees and expenses incurred in bringing this claim.

Please be advised the Respondents have thirty (30) days under the Massachusetts Consumer Protection Statute in which to tender a reasonable offer of settlement. If Respondents refuse in bad faith to grant relief upon this demand within the applicable period and with knowledge or reason to know that their acts or practices violated the Consumer Protection Statute or consumer protection laws of other states, the Claimant and the Class are entitled to up to three but not less than two times their actual damages. Should Respondents fail to grant such timely relief, the Claimant, on behalf of himself and the Class members, will institute a claim seeking treble damages, interest, attorneys' fees and costs.

Please send your response to the undersigned.

Sincerely yours,

Dennis J. Kelly

cc: Russell Surette, Client
Lawrence P. Murray, Esquire